UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:25-cv-0174-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court is Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively, "Plaintiffs") Motion for Preliminary Injunction and Stay (ECF No. 36). Having considered the briefing and applicable legal authorities, the Court will **DENY** Plaintiffs' Motion.

BACKGROUND

A. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") generally prohibits the introduction of a "new drug" into interstate commerce without the United States Food and Drug Administration's (the "FDA") approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must submit a new drug application ("NDA"). *Id.* § 355(b)(1). The FDA adjudicates such applications and approves them only if it finds, based on the evidence before it, the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]" ("cGMP"), which "assure[s] that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it

purports . . . to possess." *Id.* § 351(a)(2)(B); *see generally* 21 C.F.R. Pts. 210, 211.

In order to protect patients and ensure a new drug's efficacy, the FDA's approval process is demanding. Each drug seeking approval must be evaluated through three increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials. The sponsor must detail every ingredient and component in its application to the FDA. 21 U.S.C. § 355(b)(1)(A)(i)–(viii). The FDA conducts inspections to ensure compliance with cGMP, *id.* § 351(a)(2)(B), reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings, and contraindications, *id.* § 352(f)(1)–(2), (n), and monitors advertising and promotion to ensure it is not misleading, *id.* §§ 321(n), 352(a)(1). The FDA also requires manufacturers to track and trace each finished product, *id.* § 360eee-1, to promptly report all adverse events, *id.* § 355(k), and to conduct further post-approval studies, *id.* § 355(o). Because of the FDA's rigorous requirements, "[o]n average, it takes 10-15 years and costs $2.6 billion to develop one new medicine."[1]

To counteract the difficulties in getting new drugs approved, Congress created incentives for companies to continue investing in the research and development of new drugs. Relevant here, Congress rewards companies for investing the necessary billions of dollars into research and development by granting them "new chemical entity exclusivity" whenever the FDA approves a new medicine for the first time. 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). This statutory exclusivity means that for five years the FDA is prohibited from approving another manufacturer's application for any drug using the same active moiety.[2] *Id.*

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[1]PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://phrma.org/policy-issues/research-development (last accessed Apr. 23, 2025).

[2]"Active moiety," defined technically in 21 C.F.R. § 314.3(b), essentially refers to the chemical component of the drug that actually works in the body, as opposed to any extra chemical additions or attachments that help with how the drug is delivered or absorbed.

In addition to subjecting all new drugs to the NDA process, the FDCA regulates situations when drug compounding is permitted. Drug compounding is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002) (internal citation omitted). For example, the FDCA allows licensed pharmacists and physicians to compound a version of an FDA-approved product to address patient-specific needs, such as creating a liquid version of a medication for a patient who has trouble swallowing solids. *See* 21 U.S.C. § 353a.

Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a (hereinafter "503A compounders")[3] are not required, *inter alia*, to follow cGMP. On the other hand, outsourcing facilities (hereinafter "503B compounders") are subject to cGMP, registration, and product reporting requirements. *Id.* § 353b. Regardless of who produces them, compounded drugs are not subject to the safety requirements that apply to FDA-approved drugs because they do not undergo the FDA's premarket review for safety, effectiveness, and quality. Due to this reduced oversight, Congress has generally prohibited compounders from producing products that "are essentially copies of a commercially approved drug." *Id.* § 353a(b)(1)(D). However, this prohibition is temporarily lifted when a drug is placed on the "shortage list." *Id.* § 353b(a)(2)(A)(ii).

The FDCA defines "shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2). Further, the FDCA requires the FDA to "maintain an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." *Id.* § 356e(a). For every drug the FDA adds to its shortage list under this provision, it is required to identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the

[3]Section 353a of Title 21 of the United States Code is referred to as Section 503A within the FDA Modernization Act of 1997. Pub. L. No. 105-115 (1997).

shortage as determined by the [FDA]." *Id.* § 356e(b)(1)–(4). When a drug is placed on the FDA's shortage list, Congress permits 503A compounders to compound copies of the drug and 503B compounders to compound from that drug's active ingredient—which is otherwise prohibited—including by compounding drugs that are "essentially a copy" of an approved drug. *See Id.* §§ 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A). Because, as discussed above, compounders are subject to less oversight than drug manufactures, the FDCA permits this type of compounding only while a shortage persists.

B. Factual and Procedural Background

The drugs relevant to this case are Ozempic® and Wegovy® (collectively, the "Novo Drugs"). The FDA approved the Novo Drugs pursuant to Intervener Novo Nordisk Inc.'s ("Novo") marketing applications in 2017 and 2021, respectively. The Novo Drugs are composed of semaglutide, which is a glucagon-like peptide-1 receptor agonist. In English, the Novo drugs target and mediate chronic diseases like diabetes, obesity, kidney disease, and cardiovascular disease. The FDA has approved Ozempic® for multiple uses to assist patients with type 2 diabetes mellitus and kidney disease. And the FDA approved Wegovy® for multiple uses including treating adults with cardiovascular disease and treating obesity in patients twelve and older.

In 2022, the Novo Drugs were added to the FDA's shortage list. The FDA's placement of the Novo Drugs on its shortage list allowed for copies of the drugs to be compounded. The Novo Drugs remained on the shortage list until February 21, 2025, when the FDA issued a declaratory order removing the Novo Drugs from the list (hereinafter, the "Delisting Action"). The FDA's Delisting Action was memorialized in two documents. The first, the "Decision," presented the FDA's evidence and reasoning. The second, the "Order," summarized the FDA's reasoning and provided that the FDA would delay enforcement. Three days later, on February 24, 2025, Plaintiffs filed this lawsuit. Thereafter, on March 3, 2025, Novo filed its Motion to Intervene, which the Court granted on March 4, 2025 (collectively with the Federal Defendants, the "FDA Defendants"). Upon the Parties' motion, the Court set a briefing schedule for the present Motion. The Parties, and

Amici Curiae, have filed their respective briefs and the Motion is ripe for determination.[4]

LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" and will be granted only if the movants carry their burden on four requirements. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). The movants must show: "(1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) the threatened injury to the movant outweighs the threatened harm to the party sought to be enjoined; and (4) granting the injunctive relief will not disserve the public interest." *City of Dall. v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017) (cleaned up). "The decision to grant or deny a preliminary injunction is discretionary with the district court." *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

The Court begins with Plaintiffs' likelihood of success on the merits. For the reasons stated *infra*, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of their claims, which is the most important (and usually decisive) factor. *See*

[4]The Court notes that Plaintiffs' Reply is replete with new arguments and some 700 pages of new evidence. *See* ECF Nos. 60, 61. When new evidence or arguments are raised in a reply, a court may strike the evidence or arguments. *See Smith v. Wells Fargo Bank N.A.*, No. 3:19-CV-02406-X-BT, 2022 WL 4098031, at *1 (N.D. Tex. Aug. 2, 2022) (Rutherford, J.), *report and recommendation adopted,* No. 3:19-CV-02406-X-BT, 2022 WL 4100817 (N.D. Tex. Sept. 6, 2022) (Starr, J.) (citing *Penn. Gen. Ins. Co v. Story*, No. 3:03-cv-0330-G, 2002 WL 21435511, at *1 (N.D. Tex. June 10, 2003) (Fish, C.J.)). This is because allowing new argument and evidence in a reply "would deprive the non-movant of a meaningful opportunity to respond." *Smith*, 2022 WL 4098031, at *1 (internal quotation omitted). Here, due to the Parties' shared position that time is of the essence and the Court must rule expeditiously, the Court finds it appropriate to strike the new argument and evidence rather than ordering sur-replies which would only delay the Court's ruling on this Motion. Therefore, for the purposes of this Motion, the Court does not consider any of the new arguments or evidence presented in Plaintiffs' Reply.

Tesfamichael v. Gonzales, 411 F.3d 169, 176 (5th Cir. 2005); *Baird v. Bonta*, 81 F.4th 1036, 1041 (9th Cir. 2023). While the Court's analysis could end there, in an abundance of caution, the Court will briefly address the other preliminary-injunction elements.

A. Likelihood of Success on the Merits

Plaintiffs' Complaint raises six claims as to why the FDA's Delisting Action should be set aside. *See generally* ECF No. 1. Plaintiffs, in their Motion for Preliminary Injunction, do not address their unlawful interpretation claim under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). *See generally* ECF No. 37. Consequently, the Court does not address it here. Thus, the Court begins its analysis with Plaintiffs' two claims that are predicated on the Delisting Action being a rule before turning to Plaintiffs' three arbitrary and capricious claims.

1. Notice-and-Comment and Failure to Publish Claims

As Plaintiffs noted in their Motion, their arguments here are the same ones they raised on this issue in the sister case involving different drugs. *See Outsourcing Facilities Association, et al., v. United States Food and Drug Admin., et al.* ("*OFA I*"), No. 4:24-cv-953-P at ECF No. 65. The Court thoroughly analyzed and ultimately rejected these arguments in that case. *See OFA I*, No. 4:24-CV-0953-P, 2025 WL 746028, at *4–*8 (N.D. Tex. Mar. 5, 2025) (Pittman, J.). A decision the Fifth Circuit seemingly agrees with. *See Outsourcing Facilities Association, et al., v. United States Food and Drug Administration, et al.*, No. 25-10385 at ECF No. 98-1 ("For substantially the reasons given by the district court in its thorough opinion explaining its denial of a preliminary injunction, we find that Plaintiffs-Appellants have not made their 'clear showing.'").The Court fully adopts that reasoning and conclusion here. However, the Court wishes to illuminate its findings on one issue.

In the Court's order in *OFA I*, the Court found that notice-and-comment rulemaking is inconsistent with Congress's mandate that the shortage list be up to date. The Court reaches the same conclusion here but wishes to clarify that the distinction between rulemaking and adjudication lies in the date of the agency action relative to the most

recent age of the data being considered. For example, imagine the FDA posted its proposed rule for notice and comment on December 1, 2024, based on data from June 1, 2024 to November 30, 2024. The FDA then conducts an expeditious notice-and-comment process and issues its final rule on June 1, 2025. The most recent data relied on in issuing that rule is now seven-months old and, thus, is not "up-to-date." In contrast, if the FDA had proceeded through adjudication, as it did here, the decision could have been issued within days or weeks of the last date covered by the data. Consequently, the Court's ruling that notice-and-comment rulemaking is incongruent with Congress's up-to-date mandate is not inconsistent with the FDA choosing to look at a period of time greater than just the preceding month. The statutory scheme provides the FDA with the discretion to determine the relevant time period. As long as that time period includes the latest information available—such as data from January 2025 while making a determination in February 2025—it is entirely consistent with Congress's mandate. Accordingly, the Court finds that Plaintiffs are unlikely to succeed on their notice-and-comment and failure to publish claims.

2. Arbitrary and Capricious Claims

The Court now turns to whether Plaintiffs have demonstrated a likelihood of success on the merits because the FDA's Delisting Action was arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (citing *Medina Cnty. Env't Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Texas Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (cleaned up). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC*

v. Prometheus Radio Project, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n,* 120 F.4th at 504.

Here, Plaintiffs assert the Delisting Action is arbitrary and capricious because: (1) the FDA relied on Novo's demand presentation, [redacted] and [redacted]; (2) even Novo's demand calculations, taken at face value, reveal a shortage of over [redacted] between [redacted]; (3) the FDA relied on Novo's inventory data but failed to address numerous glaring red flags and internal inconsistencies in that data; and (4) the FDA improperly dismissed data from wholesalers that directly contradicts Novo's representations to the FDA. *See* ECF No. 37 at 6–18. The Court will address each in turn.

a. Demand Calculation

Plaintiffs first argue the Delisting Action is arbitrary and capricious because "the FDA improperly relied on data defining demand for semaglutide in a way that excludes the possibility of shortage." ECF No. 37 at 7. Plaintiffs claim that because the demand data is based on Novo's [redacted], there will "never be a shortage because by definition there will always be enough product to [redacted]." *Id.* Thus, Plaintiffs assert the demand calculation is arbitrary and capricious because it fails to account for [redacted]. *Id.* at 8–9. In their Responses, the FDA Defendants seemingly concede that the damages' calculation model is erroneous. *See* ECF No. 53 at 7 ("Of course, [redacted]—standing alone—determine whether there is a shortage."). However, the FDA Defendants contend that despite this supposed deficiency the Delisting Action is not arbitrary and capricious because the "FDA relied on a broad range of data in reaching its reasoned conclusion that supply exceeded demand." *Id.* Further, the FDA Defendants assert that the extensive evidence of inventory surplus resolves any question Plaintiffs might raise regarding a different demand calculation revealing a

shortage. *Id.* at 8. And Plaintiffs agree. ECF No. 37 at 13 ("The FDA also relies on Novo Nordisk's inventory reports. This approach has some initial intuitive appeal: If a manufacturer sells 1,000 widgets a month and has an inventory of a billion widgets, one could safely say that its supply exceeds demand."). Since, as discussed below, the Court finds the FDA decision to rely on Novo's inventory data was not unreasonable in light of the evidence before it, and data demonstrates a surplus of inventory, Plaintiffs have failed to demonstrate a likelihood of success on the merits of this claim.

b. Face value of the numbers

Next, Plaintiffs claim that even accepting the data that the FDA relied upon as true, it reveals a shortage. ECF No. 37 at 9–13. In support of their assertion, Plaintiffs raise two arguments. *First*, Plaintiffs point to Tables and Figures in the Delisting Action for the proposition that demand outpaced supply for the relative time period. *Id.* at 9–11. And *second*, Plaintiffs assert that the Tables reveal that [redacted]. *Id.* at 11–13.

Plaintiffs first argue the data provided in Tables 4 and 5 and Figures 1 and 2 evidence a shortage of [redacted] for the relevant time period. *Id.* at 9–11. However, as pointed out by the FDA Defendants, Tables 4 and 5 demonstrate the [redacted], but do not include [redacted].[5] In the Delisting Action, the Tables Plaintiffs rely upon were used to demonstrate a specific metric and, thus, demonstrate only a portion of total supply. ECF No. 37-1 at 12–14. Plaintiffs improperly attempt to combine different charts, depicting different metrics, to show a shortage. Accordingly, Plaintiffs are unlikely to succeed on this issue.

Plaintiffs' second argument, that the Tables demonstrate a shortage based on Novo's [redacted], is similarly unlikely to succeed. Plaintiffs correctly point out that the data reveals that Nova [redacted] ECF No. 37 at 11–13.

[redacted]

However, the FDA was presented with evidence that: (1) many of the [redacted]; (2) Novo had communicated [redacted]; and (3) the [redacted]" ECF No. 37-1 at 10–11. Therefore, the Court concludes it was not unreasonable in light of the evidence before it for the FDA to find that [redacted] did not evidence a shortage. Consequently, Plaintiffs are not likely to succeed on this claim.

c. Inventory data

Next, Plaintiffs claim the FDA's reliance on Novo's inventory data was erroneous for four reasons.[6] ECF No. 37 at 13–16. *First*, Plaintiffs argue Novo's inventory numbers [redacted], demonstrating a shortage. *Id.* at 14. *Second*, Plaintiffs assert Novo's inventory numbers "triple-count" doses and, thus, are not reflective of the actual numbers. *Id.* at 14–15. And *third*, Plaintiffs claim the data in Table 3 "does not even come close to matching corresponding data that Novo [ ] presents in other tables." *Id.* at 15–16. For the reasons set out below, the Court finds Plaintiffs are unlikely to succeed on any of these claims.

Plaintiffs, citing to Tables 2 and 5, claim that Novo "[redacted]" *Id.* at 14. In support of this argument, Plaintiffs cite to Novo's reported inventory (Table 2) and compare it with wholesaler orders (Table 5). *Id.* In doing so, Plaintiffs point out that the [redacted]. *Id.* While Plaintiffs' math is correct, their argument fails because it missed that Table 2's inventory numbers are based upon "the amount of finished product on average in a given month maintained in stock *after all open orders from all customers had been filled*." ECF No. 37-1 at 6 (emphasis added).

[6]Plaintiffs first assert that if [redacted] . . . ." Because this issue was addressed in the preceding section, the Court does not rehash it here.

Thus, the Table 2 inventory numbers are the numbers of doses available ***after*** Novo's [redacted]. As a consequence, the proper metric to consider whether Novo had sufficient inventory to meet the [redacted] would be a comparison of the [redacted]. Applying this principle, the FDA concluded that Novo "[redacted]." ECF No. 37-1 at 11. Based on the above, Plaintiffs have failed to demonstrate they will be successful on their claim that the FDA's conclusion was unreasonable in light of the evidence before it.

Next, Plaintiffs assert Novo's numbers "triple-count" doses and, thus, are not reflective of the actual inventory numbers. ECF No. 37 at 14. Specifically, Plaintiffs argue Novo triple-counts doses as they move through the supply chain because Novo considers a dose to be in inventory [redacted] *Id.* However, Plaintiffs' claim is based on a misconstruction of how the average monthly inventory is calculated. As Plaintiffs point out, Table 1 depicts net inventory data as of [redacted]. *See* ECF No. 37-1 at 7. At any point in time a dose can only be in one location. Thus, each dose will [redacted]. Consequently, as explained by the FDA Defendants, a monthly average inventory is [redacted]. *See* ECF No. 53 at 14. This procedure prevents doses from being over counted. Therefore, Plaintiffs have failed to demonstrate that the FDA unreasonably relied on this data and, thus, have not shown a likelihood of success on the merits of this issue.

Finally, Plaintiffs claim the data in Table 3 "does not even come close to matching corresponding data that Novo [ ] presents in other tables." ECF No. 37 at 15–16. Specifically, Plaintiffs argue:

> Novo Nordisk's "stock levels" report in Table 3 should have been a blazing red flag for the FDA. Table 3 reports the "days on hand" of Ozempic and Wegovy by dosage strength. According to Novo Nordisk's data, stock levels [redacted]

[redacted] were sufficient to [redacted], respectively. By [redacted], however, the "days on hand" of these respective dosages had [redacted]. In other words, in just [redacted] stock levels of these drugs respectively [redacted]. The same thing happened with [redacted]: between the [redacted], stock levels of [redacted]. The fact that the worth of supply were [redacted] is facially obvious evidence that the worth of supply figures are flat wrong—it should [redacted] of supply to be used.

. . .

As noted, Table 3 indicates that in [redacted] inventory levels representing [redacted] "days on hand" of [redacted]. In other words, [redacted]. But Tables 2 and 6 show that [redacted] average inventory of [redacted] during this period. And the most conservative estimate of daily demand for this period— one that substantially understates demand— is the [redacted] as reported in Table 8, divided by the [redacted], which indicates a [redacted] demand for at least [redacted]. Using this conservative figure, the [redacted] average inventories of [redacted] had sufficient stock to satisfy [redacted]. This is nowhere near the stock level of [redacted] that Novo Nordisk reports in Table 3. Put another way, to have [redacted] (as reported in Table 3), [redacted] at a bare minimum would need to have [redacted] alone—yet Tables 2 and 6 show that the [redacted] inventory for [redacted]. Like the other red flags in the Decision, the FDA failed to even recognize this issue let alone address it.

Id. (internal emphasis omitted).

As noted by the FDA Defendants, all of Plaintiffs' points on this issue are resolved by the FDA's acknowledgment of a scrivener's error it committed when creating Table 3. *See* ECF No. 53 at 14–15 ("In collating, into Table 3, Novo Nordisk's numerous reports of its finished inventory, FDA inadvertently copied in two instances [redacted]) a different data point reporting the [redacted] supply of [redacted], leading to Table 3 depicting a 'spike' that never occurred."); ECF No. 51 at 8 n.3 ("[T]wo columns of data in Table 3 mistakenly reported Novo's numbers for [redacted] days on hand rather than [redacted] days on hand. This transcription error is immaterial because FDA had before it and considered the correct information in Novo's submissions; the actual values supported FDA's conclusion that Novo 'has been maintaining substantial product in inventory;' and the [redacted] carried far less weight in the shortage determination than the [redacted]."). Further, it is evident that the FDA had the correct data in front of it when promulgating the Delisting Action. *See* ECF Nos. 53 at 14–15, 51 at 8 n.3. Moreover, in the Delisting Action, the FDA relied upon Table 3 to demonstrate a fact that is unaffected by the scrivener's error and distinct from the issues raised by Plaintiffs. *See* ECF No. 37-1 at 8 (finding that in [redacted], Novo had "at least [redacted] and [redacted] of those products."). Therefore, the Court finds Plaintiffs have failed to demonstrate that the FDA's decision was unreasonable in light of the evidence before it with regard to this issue, and thus the Court finds that Plaintiffs' have failed to demonstrate a likelihood of success on the merits of this issue.

d. Countervailing evidence

Finally, Plaintiffs assert the Delisting Action "arbitrarily waved away all evidence of shortage." ECF No. 37 at 16–18. Specifically, Plaintiffs claim that the FDA reviewed all of the evidence provided by Plaintiffs, and others, with "hyper-skepticism." *Id.* at 16. Plaintiffs raised these same arguments in *OFA I*. *See Outsourcing Facilities Association,* 4:24-cv-953-P at ECF No. 65. The Court thoroughly

addressed them and found that "the FDA's treatment of the evidence submitted by Plaintiffs, and others, was reasonable based on the evidence it had before it." *OFA I*, 2025 WL 746028, at *12–14. The Court fully incorporates and adopts that reasoning and conclusion here. Thus, the Court will only address the issues presented here by way of summary.

Here, Plaintiffs argue that the FDA erred by considering the [redacted] provided by Novo to be better evidence than Plaintiffs' website screenshots. It is not unreasonable for the FDA to consider detailed and comprehensive evidence to be more persuasive than website screen shots, some of which were undated. Plaintiffs also claim the FDA "irrationally dismissed the volume of semaglutide compounding as 'small relative to Novo[]'s production and inventory.'" ECF No. 37 at 18. In support of this argument, Plaintiffs estimate that compounders supply 520,000 doses a month of their versions of the Novo Drugs. *Id.* The data considered by the FDA in the delisting action provides that Novo supplied [redacted] of semaglutide injections in [redacted], while still retaining a net inventory of [redacted] and another [redacted] ECF No. 37-1 at 29-32. Thus, the Court finds that it was reasonable for FDA to conclude, given the evidence that it had before it, that Novo would be able to absorb 520,000 units of monthly compounder production. Accordingly, the Court finds Plaintiffs are not likely to succeed on this issue.

B. Irreparable Injury

Even enormous harms can be compensable by money damages, thus failing to justify injunctive relief. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974). But monetary damages are off the table here, as Plaintiffs sued the federal government. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021). And "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (internal citation omitted); *see Rest. Law Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023). Here, without a preliminary injunction, Plaintiffs will suffer unrecoverable financial

losses, which constitutes irreparable harm. *White Lion Invs., LLC*, 16 F.4th at 1142. Thus, this factor ways in favor of Plaintiffs.

C. Public and Private Interests

Finally, Plaintiffs must show, if the injunction is denied, the threatened injury outweighs any harm that will result if the injunction is granted, and the granting of an injunction will not disserve the public interest. *See Mock v. Garland*, 75 F.4th 563, 577 (2023). These factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). On one hand, if the Department is enjoined, it "suffers the irreparable harm of denying the public interest in the enforcement of its laws." *Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017). On the other, "it is always in the public interest" to stop enforcement of unconstitutional or invalid laws. *See Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 n.9 (5th Cir. 2014) (internal citations omitted). The Parties' arguments for both interests are the same.

Plaintiffs argue if the Court denies an injunction, patients will be deprived of their medications. ECF No. 37 at 25. The FDA Defendants claim if the Court grants an injunction, patients will continue to be subject to dangerous compounded versions. ECF Nos. 51 at 23–25; 53 at 22–23. Congress considered both of these interests in crafting the relevant regulatory scheme. If Congress thought it prudent to account for both of the asserted public interests at issue here, it is not for this Court to make a policy determination on which is greater. Thus, just as in *OFA I*, the Court finds that the public and private interests at issue in this case are a wash and do not weigh in favor of or against the granting of an injunction.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Preliminary Injunction and Stay is **DENIED.**

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the

opinion is filed, the Parties will be provided, via email, an unsigned PDF version of the order. It is **ORDERED** that, **on or before 4:00 p.m., April 29, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **24th day of April 2025.**

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE